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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,758	05/15/1998	DENNIS R MORRISON	MSC-22939-1-	8692

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/079,758	Applicant(s) MORRISON ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/24/2002, 11/20/2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,9-35,37-41,43,44,49,50,55,56,69 and 72-92 is/are pending in the application.
- 4a) Of the above claim(s) 44,49,50,55,56,79-82 and 88-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,9-35,37-41,43,69,72-78 and 83-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/24/2002 and 11/20/2002 has been entered.

Claims 1, 6, 9-35, 37-41, 43-44, 49-50, 55-56, 69, 72-92 are pending. Applicant's election of Group I in Paper filed on June 30, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 44, 49-50, 55-56, 79-82, 88-92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed on June 30, 2003.

Applicant further election of species on Nov 26, 2003 is also acknowledged. Accordingly any polymeric moiety recited as an outer membrane in instant claim 6 is viewed to meet the limitation of outer membrane polymer.

Claims 1, 6, 9-35, 37-41, 43, 69, 72-78, 83-87 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41, 78, 83-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of the instant claims are ambiguous because the claims on its face uses the closed transitional phrase "consisting of" in line 1 of the claim, but it further adds additional limitations in line 3 of the claims by reciting "further consisting of one or more magnetic particles." Therefore, the scope of the claims is not clear because no additional limitations may be added to a claim with the closed transitional phrase "consisting of."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 11, 14, 17, 21-23, 30-35, 37-38, 40, 73-75, 85-86 are rejected under 35 U.S.C. 102(b) as being anticipated by McGinty et al US Patent 5,288,502.

The instant claims are directed to microcapsules consisting of at least one internal immiscible liquid phase, an energy absorbing composition such as sorbitan monooleate, sorbitanmonooleate/ethylene oxide, etc., and a polymeric outershell. Applicant is informed that any microcapsule that contains these three elements would

also inherently meet all functional limitations set forth in the pending claims, because the claimed function are properties of one of the above recited elements.

McGinty discloses multi-phase polymeric microspheres that anticipate the limitations of the instant claims. (abstract). McGinty's microspheres comprise internal immiscible liquid phase in the form of microemulsions (see col 4, lines 54-67). McGinty's emulsion contains a water phase and an oil phase, thus it contains at least two internal phases. McGinty teaches an outer membrane polymeric shell (see Table 1, lines 40-51 describing the polymeric wall).

McGinty comprise an internal immiscible liquid phase that comprises Tween 80 (2% sorbitan monooleate/20 moles ethylene oxide) and/or Span 80 (sorbitan monooleate). (see Table 1, col 15; col 14, lines 1-10). Such element meets the energy absorbing limitation of the instant claims. Thus, McGinty meets the limitations of the instant generic claims.

McGinty also provides for the limitations of the dependent claims. For example, McGinty discloses the use of soybean recited as an halogenated oil in the pending claim 38. (see col 14, line 4 and Table 1). McGinty teaches the use of drug, drug precursors or diagnostic agents including procainamide, an anesthetic, interferon, TPA or urokinase and steroid releasing hormones (claims 1-15). Accordingly, McGinty anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 6, 9-23, 26-35, 37-41, 43, 69, 72-78, 83-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGinty in view of Grinstaff et al US Patent 5,665,383.

The teachings of McGinty are described above. McGinty fails to explicitly recite the use of suitable polymeric shells that comprise polyethylene glycols, dextrans, polyvinyl alcohols, lecithins, or polyvinylpyrrolidone. McGinty also fails to recite various types of anti-cancer agents, antibiotics, antivirals, magnetic particles or other known bioactive agents that may be encapsulated in a polymeric microcapsule.

Grinstaff teaches various types of polymeric moieties and bioactive agents that may be used to form suitable biocompatible bioactive containing shells. (see abstract, col 8, lines 20-31). Such polymers include polyethylene glycols, dextrans, polyvinyl alcohols, lecithins, or polyvinylpyrrolidone. (see col 8, lines 40-52; col 9, lines 11-19, col 12 lines 10-33 and lines 60-67; col 27; examples 10-11). Such bioactive agents include various anticancer, antibiotics, antiviral etc... (see col 13, lines 41-col14, line30). Radio

contrasts taught by Grinstaff includes paramagnetic iron (see col 7, lines 10-16; col 16, lines 51-66; example 47). Grinstaff meets the limitations of the instant claims 27 and 72.

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute suitable polymers and bioactive agents of Grinstaff in McGinty's polymeric microcapsules because first, as suggested by Grinstaff, art equivalent synthetic and natural polymers are expected to provide suitable polymeric shells for drug delivery. Second, as taught by Grinstaff, the ordinary skill in the art would have had a reasonable expectation of success for encapsulating various types of bioactive agents within a polymeric microcapsule including those taught by McGinty for effective delivery and improvement of their therapeutic efficacy.

Claims 1, 6, 9-35, 37-41, 43, 69, 72-78, 83-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGinty in view of Grinstaff as applied to claims 1, 6, 9-23, 26-35, 37-41, 43, 69, 72-78, 83-87 above, and further in view of Jacob et al US Patent 5,985,312.

The teachings of McGinty and Grinstaff are described above. Their combined teachings fail to use ferric oxide, zinc oxide or nickel oxide particles as the magnetic particle of choice.

Jacob teaches polymeric microsphere loaded with magnetic particles such as ferric oxide, zinc oxide, and nickel oxide. (abstract, col 16, lines 25-67; col 20, line 43-col 22, line 5). Jacob's microspheres does not contain a microemulsion.

Nevertheless, it would have been obvious to one of ordinary skill in the art at the time of invention to employ commonly known magnetic particles, such as ferric oxide,

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zinc oxide, nickel oxide or combinations thereof, within McGinty's polymeric microcapsules because as suggested by Ginstaff and Jacob various types of diagnostic magnetic particles including ferric oxide, zinc oxide, and nickel oxide would have been expected to provide their diagnostic utility when encapsulated in a polymeric microcapsule or microsphere. Further, absence of showing unexpected results optimizing the concentrations of such particles would have been well within purview of the ordinary skill in the art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER